Louisiana Medicaid Finerenone (Kerendia®)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for finerenone (Kerendia®).

Additional Point-of-Sale edits may apply.

This agent may have a **Black Box Warning** and may be subject to **Risk Evaluation and Mitigation Strategy** (**REMS**) under FDA safety regulations. Please refer to individual prescribing information for details.

Approval Criteria

- The recipient has a documented diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) defined as ONE of the following (must be stated on the request):
 - Urine albumin-to-creatinine ratio (UACR) of 30 to 300 mg/g, estimated glomerular filtration rate (eGFR) 25 to 60 mL/min/1.73 m² and diabetic retinopathy; OR
 - o Urine albumin-to-creatinine ratio (UACR) of ≥300 mg/g and estimated glomerular filtration rate (eGFR) 25 to 75 mL/min/1.73 m²; **AND**
- The recipient is 18 years of age or older on the date of the request; AND
- The recipient is currently receiving at least **ONE** standard of care treatment for type 2 diabetes, and this is **stated on the request**; **AND**
- **ONE** of the following is true and **stated on the request**:
 - The recipient is currently receiving a maximum tolerated labeled dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB); OR
 - The recipient has a contraindication to angiotensin-converting enzyme (ACE) inhibitor AND angiotensin receptor blocker (ARB) therapy; AND
- By submitting the authorization request, the prescriber attests to the following:
 - o The recipient's pretreatment serum potassium level is < 5 mEg/L; AND
 - o The recipient does not have known significant non-diabetic kidney disease; AND
 - The recipient does not have a clinical diagnosis of chronic heart failure with reduced ejection fraction and persistent symptoms (New York Heart Association class II to IV); AND
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; AND
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; AND

The recipient has no concomitant drug therapies or disease states that limit the use
of the requested medication and will not receive the requested medication in
combination with any medication that is contraindicated or not recommended per
FDA labeling.

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; AND
- The recipient is currently receiving at least **ONE** standard of care treatment for type 2 diabetes, and this is **stated on the request**; **AND**
- **ONE** of the following is true and **stated on the request**:
 - The recipient is currently receiving a maximum tolerated labeled dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB); OR
 - The recipient has a contraindication to angiotensin-converting enzyme (ACE) inhibitor **AND** angiotensin receptor blocker (ARB) therapy; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval: 12 months

Reference

Kerendia (finerenone) [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; July 2021. https://labeling.bayerhealthcare.com/html/products/pi/Kerendia PI.pdf

Revision / Date	Implementation Date
Policy created / August 2021	January 2022